THE LEADER LAW FIRM
3567 E. Sunrise, #133
Tucson, Arizona 85718
Phone: (520) 575-9040
Facsimile: (520) 575-9230
SBN 012511 / PCN 64791
john@leaderlawaz.com

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF ARIZONA**

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|---|---|---|
| KAY PATTESON<br>530 E. Deone Ln.<br>Tucson, AZ 85704<br><br>Complainant,<br><br>JAMES M. KOVAKAS, Freedom of Information/ Privacy Act Officer<br>Department of Justice<br>Room 7304, 20 Massachusetts Avenue, N.W.<br>Washington, DC 20530-0001<br><br>DEPARTMENT OF JUSTICE<br>Room 7304, 20 Massachusetts Avenue, N.W.<br>Washington, DC 20530-0001<br><br>Defendants | ) | No.<br><br>COMPLAINT, VIOLATION OF 5 U.S.C. § 552, FREEDOM OF INFORMATION ACT AND THE ADMINISTRATIVE PROCEDURES ACT, 5 U.S.C. §§ 701-706 |

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

## I. INTRODUCTION

1. In this civil action for declaratory and injunctive relief, Complainant KAY PATTESON challenges the failure of Defendants JAMES M. KOVAKAS, Freedom of Information/ Privacy Act Officer and DEPARTMENT OF JUSTICE (collectively "the DOJ") to comply with Complainants Freedom of Information Act ("FOIA), 5 U.S.C. § 552, *et seq*., and seeks

an order compelling the Secretary to disclose records withheld wrongfully after an FOIA request.

## II. PARTIES

2. Complainant Kay Patteson is a resident of Tucson, Arizona

3. Defendant JAMES M. KOVAKAS, Department of Justice, is the Freedom of Information/Privacy Act Officer, and in that capacity, has ultimate responsibility for complying with FOIA. He is sued in his official capacity.

4. Defendant DEPARTMENT OF JUSTICE is an agency required by law to comply with FOIA.

## III. JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to the Freedom of Information Act, 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331 (federal question jurisdiction).

6. FOIA provides this Court with "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B).

7. Venue is properly in this Court pursuant to 28 U.S.C. § 1391(e) and 5 U.S.C. § 552(a)(4)(B); because Complainant Kay Patteson resides in the District of Arizona:

> (B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant.
>
> *5* U.S.C. §*552*(a)(*4*)(B):

8. Complainant has exhausted her administrative remedies by appealing the Government's refusal to comply with her FOIA request.

9. On May 11, 2010, Complainant properly served her Freedom of Information Act Request

10. On February 18, 2011 – the Defendant formally denied Complainant's claim.

11. On March 15, 2011, Claimant timely appealed the denial of her request.

12. April 4, 2011, the Defendant acknowledged receipt of Complainant's appeal.

13. To date, the Defendants have not ruled on or responded to Claimant's appeal.

14. Pursuant to 5 U.S.C. §552(a)(6)(A)(ii), the Defendants had twenty (20) business days from the receipt of Complainant's appeal to rule on said appeal. Twenty (20) business days from March 29th was April 26, 2011 and the Defendants did not respond.

15. Under 5 U.S.C. § 552(a)(6)(C)(i), Complainant's administrative remedies are deemed exhausted because the Defendants failed to timey rule on her appeal by April 26, 2011.

16. DOJ regulations governing FOIA provide that the requester may "consider any non-response within applicable time limits as a denial of records and file a formal appeal…or lawsuit." 43 C.F.R. § 2.12(a).

17. The FOIA states that a requester/Complainant "shall be deemed to have exhausted his administrative remedies…if the agency fails to comply with the applicable time limit provisions." 5 U.S.C. § 552(a)(6)(C)(i). Complainant has thus exhausted her administrative remedies pursuant to this statute, due to the Defendants' failure to timely respond to Claimant's appeal.

18. Complainants exercise the right to commence this action pursuant to the DOJ's FOIA regulations that deem a requester may "consider any nonresponse within these time limits as

a denial of records and file a formal appeal…or lawsuit." 43 C.F.R. § 2.12(a). Additionally, the Complainants "shall be deemed to have exhausted [its] administrative remedies…if the agency fails to comply with the applicable time limit provisions." 5 U.S.C. § 522(a)(6)(C)(i).

## IV. BACKGROUND

19. The United States Food and Drug Administration (hereafter the "FDA") "is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs …" (http://www.fda.gov/AboutFDA/WhatWeDo/default.htm).

20. Before drug companies can market and sell drugs in the United States, they must obtain FDA approval.

21. Drug companies submit applications to the FDA to market and sell drugs for specific purposes.

22. In or around 1997, the "AstraZeneca" drug companies obtained FDA approval to market and sell "Seroquel", an atypical anti-psychotic, for the limited purposes of treating schizophrenia and bipolar disorder.

23. Under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §301 *et. seq*., it is illegal for drug companies to market / promote their drugs for "off label uses".

24. Title 21, United States Code §331(a) prohibits "the introduction or delivery for introduction into interstate commerce of any … drug … that is … misbranded".

25. Under Title 21, United States Code §352(f)(1), a drug is "misbranded" if it does not contain adequate directions for use.

26. A drug that is marketed and introduced into commerce for "off label" uses is "misbranded" because it does not and cannot contain adequate directions for non-approved, "off label" uses because those uses are not F.D.A. approved.

27. Marketing drugs for "off label" purposes presents dangers and threats to public safety created when drug companies market drugs for non-approved uses.

28. Before the FDA approves drugs for any given use, extensive evaluation and study is done to ensure that the drug in question is adequately safe for the use in question.

29. In recent years, the FDA has cracked down on drug company "off label" marketing. As discussed above, and in more detail below, on April 28, 2010 two AstraZeneca drug companies agreed to pay $520 million plus interest to resolve allegations that they illegally and fraudulently off label marketed Seroquel.

30. Numerous other pharmaceutical companies have settled government investigations into health care off label marketing fraud in the last few years, including (a) Pfizer, which agreed to pay $2.3 billion in September, regarding the drug Nuerontin, (b) Eli Lilly, which paid $1.4 billion in September, 2009 to settle criminal and civil charges relating to off label marketing of Zyprexa (which, like Seroquel, is an atypical antipsychotic); (c) Allergan agreed to pay $600 million in September, 2010; (d) Bristol-Myers Squibb paid $515 million in September, 2007; (e) Forest Laboratories agreed to pay $313 million in September, 2010 ; (e) In September, 2010, the Swedish drug company Novartis paid $422.5 million; (f) In January, 2011, the drug company GlaxoSmithKline ("GSK") agreed to pay $3.55 billion.

31. Additionally, in late January, 2011, a federal civil jury ordered Pfizer to pay $142 million based on illegal, off label marketing of Neurontin.

32. As these cases against drug companies make clear, off label market is a common yet illegal practice.

33. Prior to April, 2010, the United States Government conducted a lengthy investigation into illegal and improper drug marketing committed by the AstraZeneca group of Drug

Companies.

34. As part of this investigation, the U.S. Government obtained substantial evidence documenting illegal marketing practices by AstraZeneca, which are discussed more fully below.

35. FOIA requires that federal agencies respond to public requests for documents to increase public understanding of the workings of government and access to government information. The records sought by Complainant concern the United State's April 28, 2010 settlement with the "Astrazeneca" pharmaceutical companies. A copy of this Settlement Agreement is attached as **Exhibit 1**.

## V. THE APRIL 28, 2010 SETTLEMENT AGREEMENT BETWEEN THE UNITED STATES AND ASTRAZENECA

36. In 2004, James Wetta, a former AstraZeneca sales representative, filed a *qui tam*, or "whistleblower" suit against AstraZeneca, which the United States later joined. *See United States of America ex rel. James Wetta v. AstraZeneca Corporation*, Civil Action No. 04-3479 (E.D. Penn.).

37. In September, 2006, Stephan Kruszewski, M.D., a Pennsylvania Psychiatrist, filed a separate *qui tam*, or "whistleblower" suit against AstraZeneca, which the United States later joined. *See United States of America ex rel. Stephan Kruszewski v. AstraZeneca Corporation*, Civil Action No. 06-4004 (E.D. Penn.).

38. According to the complaint filed in *U.S. ex rel. Kruszewski v. AstraZeneca*, cause no. No. 06-4004 (E.D. Penn.), by 2005, and through illegal off label marketing, Seroquel had become the 20th best selling prescription drug in the world even though its approved usage

was for relatively uncommon conditions (only 3.6% of the U.S. population suffers from bipolar disorder or schizophrenia).

39. The *Kruszewski* complaint also alleges that by 2005, AztraZeneca had obtained approximately a 25% market share for the atypical anti-psychotic market (para. 5, *Kruszewski* complaint), with annual sales exceeding $1 billion, the bulk of which was related to "off label" promotion (paragraphs 52-54).

40. In 2004, AstraZeneca had sales of $17 billion related to Seroquel. Source: (http://www.nytimes.com/2009/10/30/business/30drug.html?_r=2).

41. In the April 28, 2010 Settlement Agreement, the United States alleges that AstraZeneca committed numerous illegal, fraudulent and improper acts in marketing Seroquel, including off label marketing.

42. First, the United States alleged that AstraZeneca engaged in illegal off label marketing and promotion of Seroquel, specifically, that it "promoted the sale and use of Seroquel to psychiatrists, other physicians (including primary care physicians) and other health care professionals in pediatric and primary care physicians offices, in long term care facilities and hospitals and in prisons for certain uses that were not approved by the Food and Drug Administration as safe and effective for those uses (including sleeplessness, aggression, Alzheimer's disease, anger management, anxiety, attention deficit hyperactivity disorder, bipolar maintenance dementia, depression, mood disorder and post-traumatic stress disorder." *Settlement Agreement, page 3.*

43. The United States next alleges that AstraZeneca created phony studies and literature showing that Seroquel was safe for off label uses, specifically that AstraZeneca "promoted the unapproved uses by engaging in the following conduct: You improperly and unduly

influenced the content of and speakers in company-sponsored Continuing Medical Education programs, engaged doctors to give promotional speaker programs you controlled on unapproved uses for Seroquel, engaged doctors to conduct studies on unapproved uses of Seroquel, recruited doctors to serve as authors of articles largely prepared by medical literature companies about studies they did not conduct on unapproved uses of Seroquel; and, used those studies and articles as the basis for promotional messages about unapproved uses of Seroquel. These unapproved uses were not medically accepted indications for which the United States and the state Medicaid programs provided coverage for Seroquel." *Settlement Agreement, page 3.*

44. The United States also alleges that AstraZeneca paid improper kickbacks / bribes to those it hired to create the phony studies and literature relied upon to illegally market Seroquel, specifically, that AstraZeneca "offered and paid illegal remuneration to doctors: (a) you recruited to conduct studies for unapproved uses, (b) you recruited to serve as authors of articles written by AstraZeneca and its agents about these unapproved uses of Seroquel, (c) to travel to resort locations to "advise" AstraZeneca about marketing messages for unapproved uses of Seroquel, and (d) you recruited to give promotional lectures to other health care professionals about unapproved and unaccepted uses of Seroquel. The United States contends that these payments were intended to induce the doctors to promote and/or prescribe Seroquel for unapproved uses in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b)." *Settlement Agreement, page 3.*

45. Based on these allegations, AstraZeneca agreed to repay the government $520 million plus 3% interest based on monies it illegally took from the United States of America and participating States, for prescriptions that Medicare paid for improper "off label" Seroquel

prescriptions (Medicare paid out substantial sums for "off label" use prescriptions of Seroquel).

46. Although AstraZeneca agreed to pay $520 million plus interest, it denied any wrongdoing: "AstraZeneca expressly denies the allegations of the United States … as set forth herein and denies that it has engaged in any wrongful conduct". *Settlement Agreement, page 4, paragraph "I"*.

47. The April 28, 2010 Settlement Agreement does not preclude the United States from bringing criminal charges against AstraZeneca.

## VI. COMPLAINANT KAY PATTESON – A VICTIM OF OFF LABEL MARKETING

48. Complainant Kay Patteson took Seroquel from June, 2006 through August, 2007, for an "off label" purpose – it was prescribed as a sleeping pill. Mrs. Patteson has never suffered from bipolar disorder or schizophrenia, the two conditions Seroquel is FDA approved to treat.

49. Mrs. Patteson now suffers from a severe neurologic condition known as Tardive dyskinesia, that her treating Neurologists have concluded was caused by Seroquel. Mrs. Patteson is profoundly disabled because of Seroquel, a drug designed for people with severe mental diseases that Complainant did not ever have; Complainant took Seroquel for an off label purpose (as a sleeping pill).

50. Complainant Kay Patteson has litigation pending against AstraZeneca in the U.S. District Court for the District of Columbia, that is, Cause No. Case No. 10-CV-01760-JEB, based on AstraZeneca's improper off label marketing. That action was filed September 8, 2010.

## VII. COMPLAINANT'S FOIA REQUEST

51. On May 11, 2010 Complainant Patteson submitted an FOIA request to DOJ, attached hereto as **Exhibit 2**, seeking agency records in the Government's possession relating to AstraZeneca's off label marketing.

52. In that request, Complainant sought production of all documents that the United States relied upon in alleging, as discussing in paragraphs 30, 31 and 32 of the April, 201 Settlement Agreement, that AstraZeneca (a) illegally marketed Seroquel for "off label" uses; (b) that it created phony studies and literature as part of its marketing scheme, and; (c) that it paid kickbacks and bribes to those it retained to create the phony literature and studies.

53. By letter dated February 18, 2011, the Defendants, United States of America and James M. Kovakas, identified numerous responsive documents that it refused to produce. A copy of the Feb. 18, 2011 correspondence is attached hereto as **Exhibit 3**.

54. On March 31, 2011, Complainant timely appealed the Defendants' refusal to provide the subject responsive documents. **Exhibit 4**.

55. In this action, Complainant seeks a court order requiring the DOJ to immediately produce two responsive documents identified in the Defendants' Feb. 18, 2011 correspondence.

## VIII. DOCUMENTS SOUGHT

56. In its February 18, 2011 Denial of Complainant's FOIA request, the Defendants identified sixteen (16) responsive documents that were being withheld. See Exhibit 3, at pages 3-4.

57. In this action, Complainant seeks a court order requiring the DOJ to immediately produce two of the responsive documents identified in the Defendants' Feb. 18, 2011 correspondence.

58. Pursuant to 31 U.S.C. § 3730(b)(2), a person filing a "*qui tam*" or whistleblower action must

present the Government with a written disclosure of "substantially all material evidence and information the person possesses".

59. James Wetta, the Relator in *United States of America ex rel. James Wetta v. AstraZeneca Corporation*, Civil Action No. 04-3479 (E.D. Penn.), provided the Government with a 31 U.S.C. § 3730(b)(2) Disclosure of Material Evidence on or about August 11, 2004.

60. The first wrongly withheld document that Complainant seeks production of is the document identified as "Item 1" in the Defendants' February 18, 2011 Denial, described more fully as an "8/11/2004 letter from Stephen Sheller to AUSA Dee Lord transmitting a copy of the Relator's Disclosure of Material Evidence".

61. With respect to "Item 1", Complainant seeks both the "Relator's Disclosure of Material Evidence" and the letter of transmission dated August 11, 2004..

62. The second wrongly withheld document that Complainant seeks production of is the document identified as "Item 9" in the Defendants' February 18, 2011 Denial, described more fully as an "10/6/2006 letter to Attorney General Alberto Gonzales from Brian Kenney relator's disclosure statement."

63. Stephen Kruszewski, M.D., the Relator *United States of America ex rel. Stephan Kruszewski v. AstraZeneca Corporation*, Civil Action No. 06-4004 (E.D. Penn.), provided the Government with a 31 U.S.C. § 3730(b)(2) Disclosure of Material Evidence on or about October 6, 2006.

64. With respect to "Item 9", Complainant seeks both the "Relator's Disclosure of Material Evidence" and the letter of transmission dated October 6, 2006.

65. In summary, Complainant Kay Patteson seeks an order from this Honorable Court directing the Defendants to produce two (2) wrongfully withheld documents identified in the

Defendants' February 18, 2011 denial letter: (1) "Item 1", the 31 U.S.C. § 3730(b)(2) Disclosure of Material Evidence dated August 11, 2004 from Relator James Wetta, and; (2) "Item 9", the 31 U.S.C. § 3730(b)(2) Disclosure of Material Evidence dated October 6, 2006 from Relator Stephan Kruszewski, M.D.

## VIII. FOIA EXCEPTIONS DO NOT APPLY

66. The Freedom of Information Act allows any person to obtain access to the records of federal agencies provided the statute's disclosure exemptions do not apply to the requested documents. 5 U.S.C. § 552.

67. The Defendants have the burden of proving that FOIA exceptions apply. *Lewis v. IRS*, 823 F.2d 375, 378 (9th Cir. 1987).

68. The philosophy of the FOIA is "full agency disclosure." *John Doe Agency v. John Doe Corp.*, 493 U.S. 146, 152, 110 S.Ct. 471, 107 L.Ed.2d 462 (1989); *see also Dep't of the Air Force v. Rose*, 425 U.S. 352, 361, 96 S.Ct. 1592, 48 L.Ed.2d 11 (1976) ("disclosure, not secrecy, is the dominant objective of the Act").

69. The FOIA's statutory exemptions "must be narrowly construed." *John Doe Agency*, 493 U.S. at 152, 110 S.Ct. 471.

70. On January 21, 2009 President Obama issued an Executive Memo declaring a presumption under FOIA that "openness prevails", and providing that:

> The Government should not keep information confidential merely because public officials might be embarrassed by disclosure, because errors and failures might be revealed, or because of speculative or abstract fears…All agencies should adopt a presumption in favor of disclosure, in order to renew their commitment to the principles embodied in FOIA, and to usher in a new era of open Government. The presumption if disclosure should be applied to all decisions

involving FOIA.

71. There is a strong public interest in favor of disclosure. *G.C. Micro Corp. v. Defense Logistics Agency*, 33 F.3d 1109, 1115 (9th Cir. 1994).

72. "[T]he test for confidentiality is an objective one." *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 766-67 (D.C. Cir. 1974), (citing *Bristol-Myers Co. v. FTC*, 424 F.2d at 938; *Benson v. GSA*, 289 F. Supp. 590, 594(W.D.Wash. 1968), *aff'd*, 415 F.2d 878 (9th Cir. 1969)). It is not dispositive under (b)(4) whether the information is of a type which would normally be made available to the public, or whether the government has promised to keep the information confidential. *See Petkas v. Staats*, 501 F.2d 887, 889-90 (D.C. Cir. 1974).

73. The 5 U.S.C. § 552(b)(4) exception applies and prevents disclosure of (1) commercial and financial information, that is (2) obtained from a person or by the government and; (3) that is privileged or confidential. *Pacific Architects & Engineers Inc. v. United States Dep't of State*, 906 F.2d 1345, 1347 (9th Cir. 1990).

74. Information is "confidential" for the purposes of the "trade secrets" exemption where disclosure of that information could cause "substantial harm to the competitive position of the person from whom the information was obtained." *G.C. Micro Corp. v. Defense Logistics Agency*, 33 F.3d 1109, 1112-13 (9th Cir. 1994) (citing *Nat'l Parks & Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C. Cir. 1974)).

75. The April 28, 2010 Settlement Agreement is a matter of public record and in it, the United States publicly alleges illegal conduct by AstraZeneca.

76. In light of these public allegations, it is unlikely, if not impossible that disclosure of the requested documents themselves would or could harm AstraZeneca's competitive position, a

requirement for § 552(b)(4)'s exception to apply.

77. As a matter of public policy, the documents at issue, which are evidence of criminal activity do not and cannot fall within 5 U.S.C. § 552(b)(4)'s "trade secret" exemption, because exempting this type of documents would encourage criminal behavior and endanger the public.

78. Congress, in passing the FOIA and its exceptions, could not have intended to protect criminal activity.

**B. The Administrative Procedure Act**

79. The Administrative Procedure Act ("APA") states that a reviewing court "shall compel agency action unlawfully withheld or unreasonably delayed", 5 U.S.C. § 706(1); and "shall hold unlawful and set aside agency action, findings and conclusions found to be arbitrary, capricious, and abuse of discretion or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

80. Under the APA, judicial review of agency action is proper, "except to the extent the statutes preclude judicial review; or agency action is committed to agency discretion by law." 5 U.S.C. § 701(a).

## VIII. CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF

### (Violation of the Freedom of Information Act)

81. Complainant realleges and incorporates by reference all the allegations set forth in this Complaint as though fully set forth below.

82. The DOJ's failure disclose the requested documents is a violation of FOIA, 5 U.S.C. § 552, and the agency's own regulations..

83. The DOJ's failure to provide the requested documents within the required timeframe violates 5 U.S.C. § 552(a)(6)(A)(i) and 5 U.S.C. § 552(a)(6)(B).

**SECOND CLAIM FOR RELIEF**

**(Violation of the Administrative Procedure Act)**

84. Complainant realleges and incorporates by reference all the allegations set forth in this Complaint, as though fully set forth below.

85. The DOJ's failure to disclose documents responsive to Complainants' request constitutes agency action unlawfully withheld and unreasonably delayed, in violation of the APA, 5 U.S.C. §§ 701-706. The DOJ's failure in this matter is arbitrary, capricious, an abuse of discretion, not in accordance with the law and without observance of procedure required by law, all in violation of the APA.

## IX. PRAYER FOR RELIEF

For the reasons stated above, Complainant respectfully requests that the Court grant the following relief:

1. Enter an Order declaring that the DOJ has wrongfully withheld responsive documents;

2. Order the DOJ to immediately make its determination with respect to Complainants' request and disclose to Complainants the following documents (1) "Item 1" identified in the Defendants' February 18, 2011 denial, that is, the 31 U.S.C. § 3730(b)(2) Disclosure of Material Evidence dated August 11, 2004 from Relator James Wetta, and; (2) "Item 9" identified in the Defendants' February 18, 2011 denial, that is, the 31 U.S.C. § 3730(b)(2) Disclosure of Material Evidence dated October 6, 2006 from Relator Stephan Kruszewski, M.D.

3. Maintain jurisdiction over this action until the DOJ is in compliance with FOIA, APA and every order of this Court;

4. Award Complainant her attorney fees and costs pursuant to 5 U.S.C. § 552(a)(4)(E)(i); and

5. Grant Complainant such other relief as the Court deems just and proper.

DATED: August 26, 2011.

**THE LEADER LAW FIRM**

/s/ John P. Leader
John P. Leader, Esq.